ACCURATUS
—LAB SERVICES—
THE ANTIMICROBIAL AUTHORITY

FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Swine Influenza A (H1N1) virus

PRODUCT IDENTITY

OXYTEAM
Lot# 12298 and Lot# 12299

TEST GUIDELINE

OCSPP 810.2200

PROTOCOL NUMBER

VIR07052716.SFLU

AUTHOR

Shanen Conway, B.S.
Study Director

STUDY COMPLETION DATE

September 9, 2016

PERFORMING LABORATORY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Virox Technologies Inc.
2770 Coventry Road
Oakville, ON L6H 6R1
Canada

PROJECT NUMBER

A21264

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Company: Virox Technologies Inc.

Company Agent: Ann Kline

Agent for Virox Technologies, Inc.
Title

Ann Kline
Signature

Date: 12-20-16

GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Environmental Protection Agency Good Laboratory Practice (GLP) regulations set forth in 40 CFR Part 160.

Submitter: _____ Date: 12-20-16

Sponsor: _____ Date: 10/20/16

Study Director: _____ Date: 9/9/16
Shanen Conway, B.S.

QUALITY ASSURANCE UNIT SUMMARY

Study: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of non-clinical laboratory studies. This study has been performed in accordance to standard operating procedures and the study protocol. In accordance with Good Laboratory Practice regulation 40 CFR Part 160, the Quality Assurance Unit maintains a copy of the study protocol and standard operating procedures and has inspected this study on the date(s) listed below. Studies are inspected at time intervals to assure the integrity of the study. The findings of these inspections have been reported to Management and the Study Director.

Phase Inspected	Date of Phase Inspection	Date Reported to Study Director	Date Reported to Management
Critical Phase Audit: Preparation of Virus Films	July 19, 2016	July 19, 2016	July 20, 2016
Draft Report	July 29, 2016	July 29, 2016	September 9, 2016
Final Report	September 7, 2016	September 7, 2016	

Quality Assurance Specialist: _____ Date: 9.9.16

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STUDY PERSONNEL

STUDY DIRECTOR: Shanen Conway, B.S.

Professional Personnel Involved:

Matthew Cantin, B.S.	- Virologist
Katherine A. Paulson, M.L.T.	- Lead Virologist
Erica Flinn, B.A.	- Virologist
Miranda Peskar, B.S.	- Associate Virologist

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A21264

Protocol Number: VIR07052716.SFLU

Sponsor: Virox Technologies Inc.
2770 Coventry Road
Oakville, ON L6H 6R1
Canada

Testing Facility: Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: OXYTEAM

Lot/Batch(s): Lot# 12298 and Lot# 12299

Test Substance Characterization
Test substance characterization as to identity, strength, purity, solubility and composition, as applicable, according to 40 CFR, Part 160, Subpart F [160.105], was documented prior to its use in the study. The Test Substance Certificate of Analysis Reports may be found in Attachments I-II.

STUDY DATES

Date Sample Received: June 17, 2016
Study Initiation Date: June 30, 2016
Experimental Start Date: July 19, 2016 (Start time: 11:35 am)
Experimental End Date: July 26, 2016 (End time: 9:53 am)
Study Completion Date: September 9, 2016

OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance for registration of a product as a virucide. The test procedure was to simulate the way in which the product is intended to be used. This method is in compliance with the requirements of and may be submitted to the U.S. Environmental Protection Agency (EPA).

SUMMARY OF RESULTS

Test Substance:	OXYTEAM, Lot# 12298 and Lot# 12299
Dilution:	1:64 defined as 2oz of test substance + 1 gallon of 200 ppm AOAC Synthetic Hard Water
Virus:	Swine Influenza A (H1N1) virus, ATCC VR-333, Strain A/Swine/Iowa/15/30
Exposure Time:	5 minutes
Exposure Temperature:	Room Temperature (20.0°C)
Organic Soil Load:	5% Fetal Bovine Serum
Efficacy Result:	Two lots of OXYTEAM (Lot# 12298 and Lot# 12299) met the performance requirements specified in the study protocol. The results indicate **complete inactivation** of Swine Influenza A (H1N1) virus under these test conditions as required by the U.S. EPA.

TEST SYSTEM

1. Virus

The A/Swine/Iowa/15/30 strain of Swine Influenza A (H1N1) virus used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-333). The stock virus was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells. The cells were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for five minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot SF-23) was removed, thawed and maintained at a refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Influenza virus on MDCK (canine kidney) cells.

2. Indicator Cell Cultures

Cultures of MDCK (canine kidney) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34). The cells were propagated by Accuratus Lab Services personnel. The cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. On the day of testing, the cells were observed as having proper cell integrity and confluency, and therefore, were acceptable for use in this study.

All cell culture documentation was retained for the cell cultures used in the assay with respect to source, passage number, growth characteristics, seeding densities and the general condition of the cells.

3. Test Medium

The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 2µg/mL TPCK-Trypsin, 25mM Hepes, and 0.2% BSA Fraction V.

TEST METHOD

1. Preparation of Test Substance

Two lots of OXYTEAM (Lot# 12298 and Lot# 12299) were tested at a dilution of 1:64 defined as 2oz of test substance + 1 gallon of 200 ppm AOAC Synthetic Hard Water (6.0 mL product + 384.0 mL water) as requested by the Sponsor. The test substance was in solution as determined by visual observation and used on the day of preparation. The prepared test substance was equilibrated to the exposure temperature prior to use.

The 200 ppm AOAC Synthetic Hard Water was prepared using 2.15 mL of Solution I and 4.0 mL of Solution II. The total volume of hard water was brought to approximately 1 liter using sterile deionized water. The 200 ppm hard water was prepared, titrated (at 202 ppm) and used on the day of testing.

2. Preparation of Virus Films

Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes).

3. Preparation of Sephadex Gel Filtration Columns

To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. The columns were then ready to be used in the assay.

4. Input Virus Control (TABLE 1)
On the day of testing, the stock virus utilized in the assay was titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. The results of this control are for informational purposes only.

5. Treatment of Virus Films with the Test Substance (TABLE 1)
For each lot of test substance, one dried virus film was individually exposed for 5 minutes at room temperature (20.0°C) to the amount of spray released under use conditions. The carriers were sprayed using 3 sprays, until thoroughly wet, at a distance of 6 to 8 inches, and held covered for the exposure time. The virus films were completely covered with the test substance. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity.

6. Treatment of Dried Virus Control Film (TABLE 1)
One virus film was prepared as previously described (paragraph 2). The virus control film was exposed to 2.00 mL of test medium in lieu of the test substance and held covered for 5 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the virus control was scraped with a cell scraper and at the end of the exposure time the virus mixture was immediately passed through a Sephadex column in the same manner as the test virus (paragraph 5). The filtrate (10^{-1} dilution) was then titered by 10-fold serial dilution and assayed for infectivity.

7. Cytotoxicity Controls (TABLE 2)
Each lot of the test substance was sprayed as previously described onto separate sterile petri dishes and held covered for the 5 minute exposure time at room temperature (20.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper and at the end of the exposure time the contents were immediately passed through a Sephadex column utilizing a syringe plunger. The filtrate (10^{-1} dilution) was then titered by 10-fold serial dilution and assayed for cytotoxicity. Cytotoxicity of the MDCK cell cultures was scored at the same time as the virus-test substance and virus control cultures.

8. Assay of Non-Virucidal Level of Test Substance (Neutralization Control) (TABLE 3)
Each dilution of the neutralized test substance (cytotoxicity control dilutions) was challenged with an aliquot of low titer stock virus to determine the dilution(s) of test substance at which virucidal activity, if any, was retained. Dilutions that showed virucidal activity were not considered in determining reduction of the virus by the test substance.

Using the cytotoxicity control dilutions prepared above, an additional set of indicator cell cultures was inoculated with a 100 µL aliquot of each dilution in quadruplicate. A 100 µL aliquot of low titer stock virus (approximately 1000 infectious units) was inoculated into each cell culture well and the indicator cell cultures were incubated along with the test and virus control plates.

9. Infectivity Assays

The MDCK cell line, which exhibits cytopathic effect (CPE) in the presence of Swine Influenza A (H1N1) virus, was used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability.

10. Statistical Methods: Not applicable

PROTOCOL CHANGES

Protocol Amendment:
Per Sponsor request, this protocol is amended to change the source of the bottles used in testing. They spray nozzles are provided by the Sponsor, and general purpose bottles are provided by Accuratus Lab Services.

Protocol Deviations:
No protocol deviations occurred during this study.

DATA ANALYSIS

Calculation of Titers

Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity (TCD_{50}), respectively, as calculated by the method of Spearman Karber.

$$\text{- Log of 1st dilution inoculated} - \left[\left(\left(\frac{\text{Sum of \% mortality at each dilution}}{100}\right) - 0.5\right) \times (\text{logarithm of dilution})\right]$$

Calculation of Log Reduction

Dried Virus Control Log_{10} $TCID_{50}$ – Test Substance Log_{10} $TCID_{50}$ = Log Reduction

STUDY ACCEPTANCE CRITERIA

U.S. EPA Submission

A valid test requires 1) that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film; 2) that when cytotoxicity is evident, at least a 3-log reduction in titer is demonstrated beyond the cytotoxic level; 3) that the cell controls be negative for infectivity. **Note:** An efficacious product must demonstrate complete inactivation of the virus at all dilutions.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121 for a minimum of five years following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. The original data includes, but is not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of the final study report.
7. Study-specific SOP deviations made during the study.

Test Substance Retention

The test substance will be discarded following study completion per Sponsor approved protocol. It is the responsibility of the Sponsor to retain a sample of the test substance.

REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1053-11.
2. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1482-12.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
4. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces - Efficacy Data Recommendations, September 4, 2012.
5. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A. and Lennette, E.T. editors. Seventh edition, 1995.
6. Blackwell, J.H., and J.H.S. Chen. 1970. Effects of various germicidal chemicals on HEP-2 cell culture and Herpes simplex virus. J. AOAC 53:1229-1236.

STUDY RESULTS

Results of tests with two lots of OXYTEAM (Lot# 12298 and Lot# 12299), diluted 1:64 defined as 2oz of test substance + 1 gallon 200 ppm AOAC Synthetic Hard Water, exposed to Swine Influenza A (H1N1) virus in the presence of a 5% fetal bovine serum organic soil load at room temperature (20.0°C) for 5 minutes are shown in Tables 1-3. All cell controls were negative for test virus infectivity.

The titer of the input virus control was 6.50 $\log_{10}$. The titer of the dried virus control was 5.00 $\log_{10}$. Following exposure, test virus infectivity was not detected in the virus-test substance mixture for either lot at any dilution tested ($\leq$0.50 $\log_{10}$). Test substance cytotoxicity was not observed in either lot at any dilution tested ($\leq$0.50 $\log_{10}$). The neutralization control (non-virucidal level of the test substance) indicates that the test substance was neutralized at $\leq$0.50 $\log_{10}$ for both lots. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was $\geq$4.50 $\log_{10}$ for both lots.

STUDY CONCLUSION

Under the conditions of this investigation and in the presence of a 5% fetal bovine serum organic soil load, OXYTEAM (Lot# 12298 and Lot# 12299), diluted 1:64 defined as 2oz of test substance + 1 gallon of 200 ppm AOAC Synthetic Hard Water, demonstrated complete inactivation of Swine Influenza A (H1N1) virus following a 5 minute exposure time at room temperature (20.0°C) as required by the U.S. EPA.

In the opinion of the Study Director, there were no circumstances that may have adversely affected the quality or integrity of the data.

TABLE 1: Virus Controls and Test Results

Effects of OXYTEAM (Lot# 12298 and Lot# 12299) Following a 5 Minute Exposure to Swine Influenza A (H1N1) Virus Dried on an Inanimate Surface

Dilution	Input Virus Control	Dried Virus Control	Swine Influenza A (H1N1) virus + Lot# 12298	Swine Influenza A (H1N1) virus + Lot# 12299
Cell Control	0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ +	+ + + +	0 0 0 0	0 0 0 0
10^{-2}	+ +	+ + + +	0 0 0 0	0 0 0 0
10^{-3}	+ +	+ + + +	0 0 0 0	0 0 0 0
10^{-4}	+ +	+ + + +	0 0 0 0	0 0 0 0
10^{-5}	+ +	0 + + 0	0 0 0 0	0 0 0 0
10^{-6}	+ +	0 0 0 0	0 0 0 0	0 0 0 0
10^{-7}	0 0	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$/100 µL	$10^{6.50}$	$10^{5.00}$	$\leq 10^{0.50}$	$\leq 10^{0.50}$

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 2: Cytotoxicity Control Results

Cytotoxicity of OXYTEAM on MDCK Cell Cultures

Dilution	Cytotoxicity Control Lot# 12298	Cytotoxicity Control Lot# 12299
Cell Control	0 0 0 0	0 0 0 0
10^{-1}	0 0 0 0	0 0 0 0
10^{-2}	0 0 0 0	0 0 0 0
10^{-3}	0 0 0 0	0 0 0 0
10^{-4}	0 0 0 0	0 0 0 0
10^{-5}	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0
TCD_{50}/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$

(0) = No test virus recovered and/or no cytotoxicity present

TABLE 3: Neutralization Control Results

Non-Virucidal Level of the Test Substance (Neutralization Control)

Dilution	Test Virus + Cytotoxicity Control Lot# 12298	Test Virus + Cytotoxicity Control Lot# 12299
Cell Control	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	+ + + +
10^{-2}	+ + + +	+ + + +
10^{-3}	+ + + +	+ + + +
10^{-4}	+ + + +	+ + + +
10^{-5}	+ + + +	+ + + +
10^{-6}	+ + + +	+ + + +
10^{-7}	+ + + +	+ + + +

(+) = Positive for the presence of test virus after low titer stock virus added (neutralization control)
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at a $TCID_{50}$/100 µL of ≤0.50 log_{10} for both lots.

ATTACHMENT I: Test Substance Certificate of Analysis- Lot# 12298

VIROX TECHNOLOGIES INC	GLP STUDY CERTIFICATE OF ANALYSIS	Issued by	Sarina Saini
		Issued on	6/10/2016

Sample Description:

Study No: 12298-Oxyteam-B&V-Accuratus
Preparation Date: 6/10/2016
Expiration Date: 6/10/2017

Test substance name: Oxyteam
Lot No:12298
Analysis date: 6/10/2016

Analytes Determined:

Name	CAS #	Test Method used
Hydrogen peroxide	7722-84-1	Virox No.1FP-Rev.4*

*This test determines the concentration of hydrogen peroxide (active ingredient) by iodometric titration with sodium thiosulfate. The method was validated by testing blank samples and samples excluding each of raw materials from the formulation along with different combinations of the raw materials excluding hydrogen peroxide to see if there is any interference of any of the raw materials in the hydrogen peroxide titration method.

Results:

Analyte 1	Replicate analyses	Amount found**	Average of all replicate analyses	Active or Technical	Specification Limits***	Initials
Hydrogen peroxide	1	4.04%	4.04%	Active	≤4.04% w/w***	SS
	2	4.04%				SS

**Details are recorded in QC control sheets
***Nominal is 4.25%, UL is 4.46%, LL is 4.04%

Analysis conducted by: Sarina Saini Date: 6/10/2016

Acceptability of Test Substance**:

☑ Acceptable ☐ Unacceptable

(**** Each individual test result and the average must fall within the "Specification Limits" in table above.)

Testing Facility: Virox Technologies Inc.
Document Reviewer: Jessica den Berg Date: 6/10/2016

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ATTACHMENT II: Test Substance Certificate of Analysis- Lot# 12299

VIROX TECHNOLOGIES INC.	GLP STUDY CERTIFICATE OF ANALYSIS	Issued by	Sarina Saini
		Issued on	6/10/2016

Sample Description:

Study No: 12299-Oxyteam-B&V-Accuratus
Preparation Date: 6/10/2016
Expiration Date: 6/10/2017

Test substance name: Oxyteam
Lot No:12299
Analysis date: 6/10/2016

Analytes Determined:

Name	CAS #	Test Method used
Hydrogen peroxide	7722-84-1	Virox No.1FP-Rev.4*

*This test determines the concentration of hydrogen peroxide (active ingredient) by iodometric titration with sodium thiosulfate. The method was validated by testing blank samples and samples excluding each of raw materials from the formulation along with different combinations of the raw materials excluding hydrogen peroxide to see if there is any interference of any of the raw materials in the hydrogen peroxide titration method.

Results:

Analyte 1	Replicate analyses	Amount found**	Average of all replicate analyses	Active or Technical	Specification Limits***	Initials
Hydrogen peroxide	1	4.04%	4.04%	Active	≤4.04% w/w***	SS
	2	4.04%				SS

**Details are recorded in QC control sheets
***Nominal is 4.25%, UL is 4.46%, LL is 4.04%

Analysis conducted by: Sarina Saini Date: 6/10/2016

Acceptability of Test Substance**:

☑ Acceptable ☐ Unacceptable

(**** Each individual test result and the average must fall within the "Specification Limits" in table above.)

Testing Facility: Virox Technologies Inc.
Document Reviewer: Jeanine den Boer Date: 6/10/2016

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Revision 0
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ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	July 19, 2016
Sponsor:	Virox Technologies Inc. 2770 Coventry Road Oakville, ON L6H 6R1 Canada
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Protocol Number:	VIR07052716.SFLU
Project Number:	A21264

Modifications to Protocol:

Per Sponsor request, this protocol is amended to change the source of the bottles used in testing. The spray nozzles are provided by the Sponsor and general purpose bottles are provided by Accuratus Lab Services.

Changes to the protocol are acceptable as noted.

Sharon Y. Conway
Study Director

7/19/16
Date

EXACT COPY
INITIALS SC DATE 9/9/16

(For Laboratory Use Only) A21264
Accuratus Lab Services Project #
Test Substance Tracking #

PROTOCOL

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Swine Influenza A (H1N1) virus

PROTOCOL NUMBER

VIR07052716.SFLU

PREPARED FOR/SPONSOR

Virox Technologies Inc.
2770 Coventry Road
Oakville, ON L6H 6R1
Canada

PREPARED BY/TESTING FACILITY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

DATE

May 27, 2016

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INITIALS DATE 9/9/16

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Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

PURPOSE

The purpose of this study is to evaluate the virucidal efficacy of a test substance for registration of a product as a virucide. The test procedure is to simulate the way in which the product is intended to be used. This method is in compliance with the requirements of and may be submitted to, one or more of the following agencies as indicated by the Sponsor: U.S. Environmental Protection Agency (EPA), Health Canada and Australian Therapeutic Goods Administration (TGA).

TEST SUBSTANCE CHARACTERIZATION

According to 40 CFR, Part 160, Subpart F [160.105] test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to Accuratus Lab Services. Accuratus Lab Services will append Sponsor-provided Certificates of Analysis (C of A) to this study report, if requested and supplied. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

SCHEDULING AND DISCLAIMER OF WARRANTY

Experimental start dates are generally scheduled on a first-come/first-serve basis once Accuratus Lab Services receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is June 20, 2016. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of July 18, 2016. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at Accuratus Lab Services.

If a test must be repeated, or a portion of it, because of failure by Accuratus Lab Services to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test.

Neither the name of Accuratus Lab Services nor any of its employees are to be used in advertising or other promotion without written consent from Accuratus Lab Services.

The Sponsor is responsible for any rejection of the final report by the regulatory agency of its submission concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the Accuratus Lab Services final report and notify Accuratus Lab Services of any perceived deficiencies in these areas before submission of the report to the regulatory agency. Accuratus Lab Services will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM

Regulatory agencies require that a specific virucidal claim for a disinfectant intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the test substance against the claimed virus. Each agency will accept adequate data generated by any appropriate technique in support of a virucidal efficacy claim. This is accomplished by treating the target virus with the disinfectant (test substance) under conditions, which simulate as closely as possible, in the laboratory, the actual conditions under which the disinfectant is designed to be used. For disinfectant products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting virological data. The MDCK cell line, which supports the growth of the Swine Influenza A (H1N1) virus, will be used in this study. The experimental design in this protocol meets these requirements.

TEST PRINCIPLE

A film of virus, dried on a glass surface, is exposed to the test substance for a specified exposure time. At the end of the exposure time, the virucidal and cytotoxic activities are removed from the virus-test substance mixture, and the mixture is assayed for viral infectivity by an accepted assay method. Appropriate virus, test substance cytotoxicity, and neutralization controls are run concurrently.

STUDY DESIGN

Dried virus films will be prepared in parallel and used as follows:

The appropriate number of films for each batch of test substance assayed per exposure time requested.

The appropriate number of films for virus control titration (titer of virus after drying) per exposure time requested.

The inoculated carriers are exposed to the test substance for the Sponsor specified exposure time. At the end of the specified exposure time, resuspended virus-test substance mixtures will be detoxified and made non-virucidal by immediately adding the contents to a Sephadex gel filtration column followed by 10-fold serial dilutions in test medium. Each dilution is inoculated into indicator cell cultures. The resuspended virus control film and each batch of test substance alone will be treated in exactly the same manner. For analysis of infectivity, cultures will be held for the appropriate incubation period at the end of which time cultures will be scored for the presence of the test virus. Cultures will be monitored at that time for cell viability. Uninfected indicator cell cultures will be carried in parallel and similarly monitored. For analysis of cytotoxicity, the viability of cultures inoculated with dilutions of each test and cytotoxicity control will be determined. In addition to the above titrations for infectivity and cytotoxicity, the residual virucidal activity of the test substance after neutralization will be determined by adding a low titer of stock virus to each dilution of the test substance (cytotoxicity control dilutions). The resulting mixtures of dilutions are assayed for infectivity in order to determine the dilution(s) of test substance at which virucidal activity, if any, is retained.

VIRUS

The A/Swine/Iowa/15/30 strain of Swine Influenza A (H1N1) virus to be used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-333). Stock virus is prepared by collecting the supernatant culture fluid from 75-100% infected culture cells. The cells are disrupted and cell debris removed by centrifugation. The supernatant is removed, aliquoted, and the high titer stock virus may be stored at ≤ -70°C until the day of use. Alternate methods of viral propagation may be utilized based on the growth requirements of the virus. The propagation method will be specified in the raw data and in the report. On the day of use the appropriate number of aliquots are removed, thawed, combined (if applicable) and maintained at a refrigerated temperature until used in the assay. Note: If the Sponsor requests an organic soil load challenge, fetal bovine serum (FBS) or the requested organic soil will be incorporated into the stock virus aliquot. The stock virus aliquot will be adjusted to yield the percent organic soil load requested.

INDICATOR CELL CULTURES

Cultures of MDCK (canine kidney) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34). The cells are propagated by Accuratus Lab Services personnel. The cells are seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. The confluency of the cells will be appropriate for the test virus. MDCK cells obtained from an alternate, reputable source may be used. The source of the cells will be specified in the final report.

All cell culture documentation is retained for the cell cultures used in this assay with respect to source, passage number, growth characteristics, seeding densities and the general condition of the cells.

TEST MEDIUM

The test medium used for this assay is Minimum Essential Medium (MEM) supplemented with 0-10% (v/v) heat inactivated fetal bovine serum. The medium may also be supplemented with one or more of the following: 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 1.0-2.0 mM L-glutamine, and 0.5 – 5 µg/mL trypsin. The composition of the test medium may be altered based on the virus and/or cells. The composition of the medium will be specified in the raw data and in the report.

PREPARATION OF TEST SUBSTANCE

The dilution of test substance(s) will be used as recommended by the Sponsor. The product will be pre-equilibrated to the desired test temperature if applicable.

PREPARATION OF VIRUS FILMS

Films of virus will be prepared by spreading 200 µL of virus inoculum uniformly over the bottom of the appropriate number of 100 X 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus will be air-dried at 10°C-30°C until visibly dry (≥20 minutes). A calibrated timer will be used for timing the drying. The drying conditions (temperature and humidity) will be appropriate for the test virus for the purpose of obtaining maximum survival following drying. The actual drying conditions, drying time and calibrated timer used will be clearly documented.

One dried virus film per batch of test substance will be assayed unless otherwise requested.

TEST METHOD

Preparation of Sephadex Gel Filtration Columns

To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus is separated from the test substance by filtration through Sephadex gel. The type of Sephadex used will be specified in the final report. On the day of testing, Sephadex columns are prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. The columns are now ready to be used in the assay.

Input Virus Control

On the day of testing, the stock virus utilized in the assay will be titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. The results of this control are for informational purposes only.

Treatment of Virus Films with the Test Substance

For each batch of test substance assayed, the appropriate number of dried virus films are individually exposed to a 2.0 mL aliquot of the use dilution of the test substance (liquid products), or to the amount of spray released under use conditions (spray products) and held covered for the specified exposure time(s) and temperature. A calibrated timer will be used for timing the exposure. The actual temperature will be recorded. Just prior to the end of the exposure time, the plates are individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures are immediately passed through individual Sephadex columns utilizing the syringe plunger in order to detoxify the mixture. The filtrate (10^{-1} dilution) is then titered by serial dilution and assayed for infectivity and/or cytotoxicity. To further aid in the removing of the cytotoxic effects of the test substance to the indicator cell cultures, individual dilutions may be passed through additional individual Sephadex columns.

Treatment of Dried Virus Control Film
The appropriate number of virus films are prepared as described previously for each exposure time assayed. The virus control films are run in parallel to the test virus but a 2.0 mL aliquot of test medium is added in lieu of the test substance. The virus control films are held covered and exposed to the test medium for the same exposure time and at the same exposure temperature as the test films are exposed to the test substance. A calibrated timer will be used for timing the exposure and the actual temperature will be recorded. Just prior to the end of the exposure time, the virus films are individually scraped as previously described and at the end of the exposure time the mixtures are immediately passed through individual Sephadex columns utilizing the syringe plunger. The filtrate (10^{-1} dilution) is then titered by serial dilution and assayed for infectivity. If additional Sephadex columns were used to further reduce the cytotoxic effects in the test substance assay, the same dilutions of the virus control will be passed through additional individual Sephadex columns.

Cytotoxicity Control
A 2.0 mL aliquot of each batch of test substance (liquid products) or the amount of the test substance recovered when sprayed onto a sterile petri dish (spray products), is filtered through a Sephadex column utilizing the syringe plunger and the filtrate is diluted serially in medium and inoculated into cell cultures for assay of cytotoxicity concurrently with the virus control and test substance-treated virus samples. For spray products, the cytotoxicity control will be held covered for the longest requested exposure time at the requested exposure temperature. A calibrated timer will be used for timing the exposure. If additional Sephadex columns were used to further reduce the cytotoxic effects in the test substance assay, the same dilutions of the cytotoxicity control will be passed through additional individual Sephadex columns.

Assay of Non-Virucidal Level of Test Substance (Neutralization Control)
Each dilution of the neutralized test substance (cytotoxicity control dilutions) will be challenged with an aliquot of low titer stock virus to determine the dilution(s) of test substance at which virucidal activity, if any, is retained. Dilutions that show virucidal activity will not be considered in determining reduction of the virus by the test substance.

Using the cytotoxicity control dilutions prepared above, an additional set of indicator cell cultures will be inoculated with a 100 µL aliquot of each dilution in quadruplicate. A 100 µL aliquot of low titer stock virus will be inoculated into each cell culture well and the indicator cell cultures will be incubated along with the test and virus control plates.

Infectivity Assays
The MDCK cell line, which exhibits cytopathic effect (CPE) in the presence of Swine Influenza A (H1N1) virus, will be used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes will be inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. The input virus control will be inoculated in duplicate. Uninfected indicator cell cultures (cell controls) will be inoculated with test medium alone. The cultures are incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware for approximately seven days. Periodically throughout the incubation time the cultures will be microscopically observed for the absence or presence of CPE, cytotoxicity and for viability. The observations will be recorded on the raw data worksheets; only the results from the final observations will be reported.

DATA ANALYSIS

Calculation of Titers
Viral and cytotoxicity titers will be expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity (TCD_{50}), respectively, as calculated by the method of Spearman Karber.

$$-\text{Log of 1st dilution inoculated} - \left[\left(\left(\frac{\text{Sum of \% mortality at each dilution}}{100}\right) - 0.5\right) \times (\text{logarithm of dilution})\right]$$

Calculation of Log Reduction
Dried Virus Control Log_{10} $TCID_{50}$ – Test Substance Log_{10} $TCID_{50}$ = Log Reduction

If multiple dried virus control replicates are performed, the average titer of the replicates will be calculated and the average titer will be used to calculate the log reduction in viral titer of the individual test replicates.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM
The specialized virucidal testing section of Accuratus Lab Services maintains Standard Operating Procedures (SOPs) relative to virucidal efficacy testing studies. Virucidal efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including virus and cell stocks for purposes of identification, receipt and use of chemical reagents including cell culture medium components, etc. These procedures are designed to document each step of virucidal efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each virucidal efficacy test is assigned a unique Project Number when the Study Director initiates the protocol for the study. This number is used for identification of the test culture plates, etc. during the course of the test. Test culture plates are also labeled with reference to the test virus, experimental start date, and test product. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: N/A

STUDY ACCEPTANCE CRITERIA
Only the applicable acceptance criteria and references for the regulatory agency reviewing the data will be included in the final report.

U.S. EPA, Health Canada, and Australian TGA Submission
A valid test requires 1) that at least 4 $\log_{10}$ of infectivity be recovered from the dried virus control film; 2) that when cytotoxicity is evident, at least a 3-log reduction in titer is demonstrated beyond the cytotoxic level; 3) that the cell controls be negative for infectivity. If any of the previous requirements are not met, the test may be repeated under the current protocol number. **Note:** An efficacious product must demonstrate complete inactivation of the virus at all dilutions.

If the test substance fails to meet the test acceptance criteria and the dried virus control fails to meet the control acceptance criteria, the study is considered valid and no repeat testing is necessary, unless requested by the Sponsor.

If any portion of the protocol is executed incorrectly warranting repeat testing, the test may be repeated under the current protocol number.

FINAL REPORT
The report will include, but not be limited to, identification of the sample and date received, dates on which the test was initiated and completed, identification of the virus strain used and composition of the inoculum, description of cells, medium and reagents, description of the methods employed, tabulated results, calculated titers for infectivity and cytotoxicity, and a conclusion as it relates to the purpose of the test. A draft report may be requested by the Sponsor. The final report will be prepared once the Sponsor has reviewed the draft report and notified the Study Director to complete the study.

PROTOCOL CHANGES
If it becomes necessary to make changes in the approved protocol, the revision and reasons for change will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

TEST SUBSTANCE RETENTION
Test substance retention shall be the responsibility of the Sponsor. Unused test substance will be **discarded** following study completion unless otherwise requested.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services for a minimum of five years for GLP studies or a minimum of six months for all other studies following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of the final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at Accuratus Lab Services. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study, which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

PROPOSED STATISTICAL METHODS: N/A

REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1053-11.
2. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1482-12.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
4. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations, September 4, 2012.
5. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A. and Lennette, E.T. editors. Seventh edition, 1995.
6. Blackwell, J.H., and J.H.S. Chen. 1970. Effects of various germicidal chemicals on HEP-2 cell culture and Herpes simplex virus. J. AOAC 53:1229-1236.
7. Health Canada, January, 2014. Guidance Document - Disinfectant Drugs.
8. Health Canada, January, 2014. Guidance Document - Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
9. Australian Therapeutic Goods Administration (TGA), February 1998. Guidelines for the Evaluation of Sterilants and Disinfectants.
10. Australian Therapeutic Goods Administration (TGA), February 1998. Therapeutic Goods Order No. 54: Standard for Disinfectants and Sterilants.
11. Australian Therapeutic Goods Administration (TGA), March 1997. Therapeutic Goods Order No. 54A: Amendment to Standard for Disinfectants and Sterilants (TGO 54).
12. Australian Therapeutic Goods Administration (TGA), July 2005. Draft Guidelines for the Evaluation of Household/Commercial and Hospital Grade Disinfectants.

STUDY INFORMATION

(All blank sections are completed by the Sponsor or Sponsor Representative as linked to their signature, unless otherwise noted.)

Test Substance (Name and Batch Number - exactly as it should appear on final report):

Oxivir Tb Lot# 12298, 12299

Testing at the lower certified limit (LCL) for the hardest-to-kill virus on your label is required for registration.

Product Description

☐ Quaternary ammonia ☐ Peracetic acid ☐ Sodium hypochlorite
☐ Iodophor ☑ Peroxide ☐ Other_____

Approximate Test Substance Active Concentration (upon submission to Accuratus Lab Services):

Lot # 12298: 4.08% Lot # 12299: 4.04%

(This value is used for neutralization planning only. This value is not intended to represent characterization values.)

Storage Conditions

☑ Room Temperature ☐ 2-8°C ☐ Other_____

Hazards

☐ None known: Use Standard Precautions
☑ Material Safety Data Sheet, Attached for each product
☐ As Follows: _____

Product Preparation

☐ No dilution required, Use as received (RTU)
☑ *Dilution(s) to be tested:

1:64 defined as 2oz + 1 gallon
(example: 1 oz/gallon) (amount of test substance) (amount of diluent)

☐ Deionized Water (Filter or Autoclave Sterilized)
☐ Tap Water (Filter or Autoclave Sterilized) - All tap water is softened; the water hardness for the batch of tap water used will be determined and reported.
☑ AOAC Synthetic Hard Water: 300 PPM
☐ Other _____

Note: An equivalent dilution may be made unless otherwise requested by the Sponsor.

Test Virus: Swine Influenza A (H1N1) virus

Exposure Time: 5 minutes

Exposure Temperature: ☑ Room temperature (to be based on regulatory agency of submission)
☐ Other:_____°C (please specify range)

Directions for application of aerosol/spray products:

☐ Spray instructions are not applicable.

Trigger spray application:

☑ Spray carriers using 3 sprays, or until thoroughly wet, at a distance of 6 to 8 inches.
☐ Spray carriers using_____ sprays at a distance of _____ to ____ inches/cm. (circle one)

Aerosol spray application:

☐ Spray carriers for _____ seconds, or until thoroughly wet, at a distance of _____ to ____ inches/cm.

Organic Soil Load

☐ 1% fetal bovine serum (minimum level that can be tested)
☑ 5% fetal bovine serum
☐ Other_____

Number of Carriers to be Tested
- ☑ One (typical for U.S. EPA submission)
- ☐ Five (required for broad-spectrum virucidal claims for Health Canada submission)

SPRAY BOTTLES USED IN TESTING (section only applicable for spray products)
To ensure expected levels of product are delivered, it is recommended that the Sponsor provide the spray bottles used in testing. Please indicate the desired source of the sprayer bottles used in testing:
- ☑ Sprayer(s) and bottle(s) are provided by the Sponsor
- ☐ General purpose spray bottle(s) are to be provided by Accuratus Lab Services
- ☐ The spray nozzle(s) are provided by the Sponsor and general purpose bottle(s) will be provided by Accuratus Lab Services

REGULATORY AGENCY(S) THAT MAY REVIEW DATA
- ☑ U.S. EPA
- ☐ Health Canada
- ☐ Therapeutic Goods Administration (Australian TGA)
- ☐ Not applicable - For internal/other use only (Efficacy result will be based on U.S. EPA requirements)

COMPLIANCE
Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures.
- ☑ Yes
- ☐ No (Non-GLP or Development Study)

PROTOCOL MODIFICATIONS
- ☑ Approved without modification
- ☐ Approved with modification

_____

_____

PROTOCOL ATTACHMENTS
Supplemental Information Form Attached - ☐ Yes ☑ No

TEST SUBSTANCE SHIPMENT STATUS
(This section is for informational purposes only.)
- ☐ Test Substance is already present at Accuratus Lab Services.
- ☑ Test Substance has been or will be shipped to Accuratus Lab Services.
  Date of expected receipt at Accuratus Lab Services: _____
- ☐ Test Substance to be hand-delivered (must arrive by noon at least one day prior to testing or other arrangements made with the Study director).

TEST SUBSTANCE CHARACTERIZATION & STABILITY TESTING
[Verification required per 40 CFR Part 160 Subpart B (160.31(d))].

☐ Characterization/Stability testing is not required (For Non-GLP or Development testing only)

OR

Physical and Chemical Characterization (identity, purity, strength, solubility, as applicable) of the test lots

☑ Physical & Chemical Characterization has been or will be completed prior to efficacy testing.

GLP compliance status of physical & chemical characterization testing:
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Characterization has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☑ A Certificate of Analysis (C of A) may be provided for each lot of test substance. If provided, the C of A will be appended to the report.
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:

_____

☐ Test has been or will be conducted by another facility under protocol or study #:

_____

☐ Physical & Chemical Characterization was not or will not be performed prior to efficacy testing.

Stability Testing of the formulation

☑ Stability testing has been or will be completed prior to or concurrent with efficacy testing.

GLP compliance status of stability testing:
(GLP compliance is required by 40 CFR Part 160)
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Stability testing has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:

_____

☑ Test has been or will be conducted by another facility under protocol or study #:

Study # 1029 RA1

☐ Stability testing was not or will not be performed prior to or concurrent with efficacy testing.

If test substance characterization or stability testing information is not provided or is not performed following GLP regulations, this will be indicated in the GLP compliance statement of the final report.

APPROVAL SIGNATURES

SPONSOR:

NAME: Mr. Babak Ghahchi TITLE: Senior Vice President of Quality Assurance and Regulatory Affairs

SIGNATURE: [signature] DATE: 06/10/16

PHONE: 1 (905) 812 - 0110 FAX: EMAIL: babak@virox.com

For confidentiality purposes, study information will be released only to the sponsor representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

Lok Chum, Faraz Ahmadpour

Accuratus Lab Services:

NAME: Shanen Conway
Study Director

SIGNATURE: [signature] DATE: 6/30/16
Study Director